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Original Article

Assessing Views on Using Surplus Human Bio Specimens for Future Research among Pharmaceutical Sponsors: A Prospective Interventional Study

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ABSTRACT

Background: Pharmaceutical sponsors have a significant responsibility in gathering and overseeing the storage of leftover human biological samples. Understanding the proper utilization and potential risks associated with these stored specimens is crucial for pharmaceutical sponsors. Educating these sponsors on biological sample research is imperative. Hence, the present study aims to assess, evaluate the Knowledge, Attitude and Practice (KAP) among pharmaceutical sponsors in relation to the utilization of surplus human biological samples for future research. **Materials and Methods:** A study was conducted in which pharmaceutical sponsors participated in both pre- and post-intervention assessments to evaluate prospective changes. Prior to the survey, self-prepared and validated Knowledge, Attitudes and Practices (KAP) questionnaires were distributed among the sponsors, uncovering certain gaps in their knowledge, attitudes and practices. Following this, health education was administered through oral sessions and leaflets. A follow-up survey was conducted one month later using the identical set of questionnaires to assess any changes in KAP among the pharmaceutical sponsors. **Results:** A research recruited 52 participants from pharmaceutical sponsors, with men greater than women by 75 percent. Most of participants (69.2%) were between the ages of 20 and 30, with 73.1% having a pharmacy background. In addition, 82.7% had between 1-5 years of work experience. Senior Clinical Research Associates (CRAs) accounted for 30.8% of participation, while CRAs made for 23.1%. The research project begins with a pre-test to assess participants' knowledge, attitude and practices, followed by an educational intervention and a post-survey one month later. The McNemar-Bowker test revealed significant improvements in scores (p-value<0.005) after the intervention. **Conclusion:** Educating pharmaceutical sponsors about leftover bio specimens reduces misuse as well as helps in understanding the ethical issues involving leftover bio specimen studies.

Keywords: Pharmaceutical Sponsors, Knowledge, Attitude and practice, HSBs: Human Surplus Bio specimens, Bioethics.

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INTRODUCTION

Bio specimens, such as blood, Serum, tissue biopsies, etc., these samples are essential in diagnosing and treating diseases.[1] The use of these samples in research leads some serious ethical considerations and challenges. Assessing views on using surplus human bio specimens for research among sponsors involves examining various perspectives and considerations within the industry. Surplus human bio specimens refer to biological materials collected during clinical trials or medical procedures that are not used for their intended purpose but can be utilized for further research.[2,3] From the perspective of sponsors, the use of surplus human bio specimens for research can offer several advantages. Firstly, it can enhance the efficiency and cost-effectiveness of clinical trials. By utilizing leftover specimens, Pharmaceutical sponsors can reduce the need for additional sample collection, thereby saving time and resources. This can be particularly beneficial in cases where obtaining fresh samples may be challenging or costly. In addition, utilizing excess human bio specimens might help in discovering of new research processes. These specimens might provide essential information about diseases causes, biomarker research and treatment response, encouraging drug manufacturers to develop novel insights into science. This will assist to develop advances medications and methods for diagnosis, which will help both subjects and medical professionals. Likewise leftover human bio specimens will be used in adherence with ethical research standards. Although these specimens have previously been collected for therapeutic purposes, using them for further research maximizes their future

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usage while minimizing wastage. This method assures that the study subjects' contributions to the field of medicine are effectively utilized while respecting their right to autonomy and the ethical issues associated with their participation in clinical trials.[4,5]

However, there are also potential challenges and concerns associated with using surplus human bio specimens for research. One major consideration is ensuring the privacy and confidentiality of subject information.[6,7] Pharmaceutical sponsors and researchers should establish strong data protection protocols to ensure the confidentiality of subjects' identities and adhere to pertinent privacy regulations. Additionally, obtaining informed consent is crucial. Although surplus human bio specimens are gathered for clinical objectives, utilizing them for research may necessitate securing additional consent from the subject's involved.[8,9] Pharmaceutical sponsors must ensure that Subject are adequately informed about the potential future uses of their specimens and have the opportunity to provide or withhold consent accordingly.[10] Furthermore, there may be logistical challenges in accessing and managing surplus human bio specimens. Pharmaceutical sponsors need to establish efficient systems for specimen storage, tracking and distribution to ensure their quality and integrity. This may involve collaborations with bio banks or specialized facilities that can provide the necessary infrastructure and expertise.[11]

Overall, assessing views on using surplus human bio specimens among research stakeholders involves weighing the potential benefits, ethical considerations and practical challenges associated with this approach.[12,13] By carefully considering these factors, researchers can develop guidelines and best practices to promote responsible and impactful utilization of surplus samples. However, these ethical concerns surrounding their use for research purposes have led to the establishment of guidelines.[14,15] Unfortunately, these guidelines vary from one country to other Country and lack uniformity, making it challenging for research stakeholders to interpret and adhere to them.

Biomaterials, which are crucial in research, require proper utilization, storage and understanding of their significance in studies. Therefore, it is important for each study procedure to provide detailed information on these aspects. To gather insights on the utilization of surplus bio specimens we conducted a KAP study involving Pharmaceutical sponsors.

Pharmaceutical sponsors play a significant role in the field of clinical trials. Current research aims to assess and evaluate their KAP, regarding leftover samples and the reuse of data for future research. We recognize the ethical challenges involved in the preparation, implementation and conduct of clinical trials, particularly in relation to optional research on leftover samples, data reuse, optional consent, storage and usage of biomaterial samples data (including genetic information) and the return of research results and benefits to the study participants.

In India, there are guidelines provided by the Indian Council of Medical Research (ICMR) for the collection and storage of biological samples and leftover sample data.[16] However, there is a lack of specific international guidelines addressing or minimizing the ethical challenges, consent-related issues and decisions regarding leftover samples in research.[17]

The goal is to enhance current knowledge by exploring the opinions and perspectives of clinical researchers concerning surplus bio specimens. This information can help inform the development of more comprehensive and standardized guidelines that address the ethical concerns surrounding the use of human bio specimens in research.

MATERIALS AND METHODS

A prospective interventional study was conducted among Pharmaceutical sponsors at metro cities in Karnataka. Pre survey was conducted by KAP, questionnaires among Pharmaceutical sponsors, before conducting the pre-survey, the study obtained approval from the Institutional Ethics Committee (IEC) at KAHER, Belagavi, Karnataka, India, with the reference number KAHER/EC/20-21/021. Additionally, the study is registered with the Clinical Trials Registry-India (CTRI) under the registration number (Reg No: CTRI/2021/11/038332), Participants with at least one year of experience actively engaged in clinical research across various pharmaceutical sponsors and their representatives were included. Participants with less than one year of experience and those under the age of 18 were excluded from the study. Following the pre-survey, a knowledge gap was identified among Pharmaceutical sponsors. To address this, educational tools were employed and participants were educated through oral explanations and face-to-face interviews during the site visit, chosen based on their convenience and feasibility for our intervention. Subsequently, one month later, a post-test was conducted using the same set of KAP questionnaires. The information was inputted and organized in Microsoft Excel. The data findings were examined using the Mcnemer-Bowker test in SPSS software version 20.0. The research is visually depicted in Figure 1.

Questionnaire Design

The Department of Clinical Research, Tertiary Care Hospital and MRC conducted a structured interview study utilizing a self-framed and validated KAP questionnaire. This study targeted various pharmaceutical sponsors in the different geographical area. The questionnaire was designed with closed-ended questions and a five-point Likert scale. It comprises of four sections, each featuring a different number of questions, covering demographic details, knowledge, attitude and practice aspects.

Study Participants

This study involved the selection of Pharmaceutical sponsors from different companies, currently occupying various designations such as CRAs, Clinical Trial Assistants, Project Managers, etc., within the field of clinical research. Participants were chosen from different locations and those who engaged in any form of clinical trial visits were screened and enrolled based on the study criteria. Overall, 52 study participants enrolled into the study as per the study requirements. Each participant provided consent and received a thorough explanation about their involvement in the study. Voluntary registrations were considered and participants were enrolled with their explicit consent, ensuring active participation while maintaining strict confidentiality.

RESULTS

Demographic profile of Pharmaceutical sponsors

The total 52 participants are enrolled into the study their demographic results are presented on their gender, age, role, work experience, educational background and location basis. In terms of gender, there are 39 male participants, accounting for 75% of the group and 13 female participants, making up 25% of the group. Regarding age, there were 36 participants aged between 20-30 years, representing 69.2% of the group. There are 13 participants aged between 31-40 years, accounting for 25% of the group. Additionally, there are 3 participants aged between 41-50 years, making up 5.8% of the group. The mean age for the group is 1.37, calculated as a weighted average. The role distribution among the participants is as follows: 8 participants are Clinical Trial Assistants (CTAs), representing 15.4% of the group. There are 12 Clinical Research Associates (CRAs), accounting for 23.1% of the group. 16 participants hold the position of Senior CRA, making up 30.8% of the group. 2 participants are QA Auditors/Managers, representing 3.8% of the group. 6 participants are Project Managers, accounting for 11.5% of the group. 2 participants are Data Analysts, making up 3.8% of the group. Lastly, there are 6 participants categorized as "Others," representing 11.5% of the group. The majority of participants (82.7%) in the study have 1-5 years of work experience, while 11.5% have 6-10 years, 3.8% have 11-15 years and 1.9% has more than 16 years of experience. The mean work experience for the group is 1.25, calculated as a weighted average. In terms of educational background, 3 participants have a background in Medicine, representing 5.8% of the group. 38 participants have a background in Pharmacy background, accounting for 73.1% of the group. 11 participants have a background in Life Sciences/Allied Sciences, making up 21.2% of the group. Table 1 provides an in-depth overview of the demographic characteristics.

Knowledge Pre and Post analysis of Pharmaceutical Sponsors by using McNemar-Bowker Test

On assessment, of knowledge levels from the survey collected from among 52 participant's pre and post intervention, assessing their knowledge related to the handling and utilization of surplus bio specimens in research. The "Pre" and "Post" columns represent the number (n) and percentage (%) of participants, respectively, for each response category. The "P Value" column indicates the statistical significance of the observed changes. Regarding knowledge about storing bio specimen samples for future research, there was a significant increase from 57.7% to 82.7% with significance ($p<0.003$). Similarly, understanding the necessity of consent for secondary research showed an increase from 78.8% to 90.4%, though not statistically significant ($p=0.182$). Consent requirement for utilizing surplus bio specimens saw a substantial rise from 48.1% to 88.5% ($p<0.000$) and recognition of the usefulness of surplus bio specimens in developing diagnostic and treatments for diseases also significantly increased from 69.2% to 94.2%. However, understanding of the necessity of investigations outlined in clinical trial protocols for surplus bio specimens in secondary research decreased from 30.8% to 11.5% ($p=0.29$), while observation of obtaining prior consent before utilizing surplus bio specimens significantly increased from 50% to 92.3%

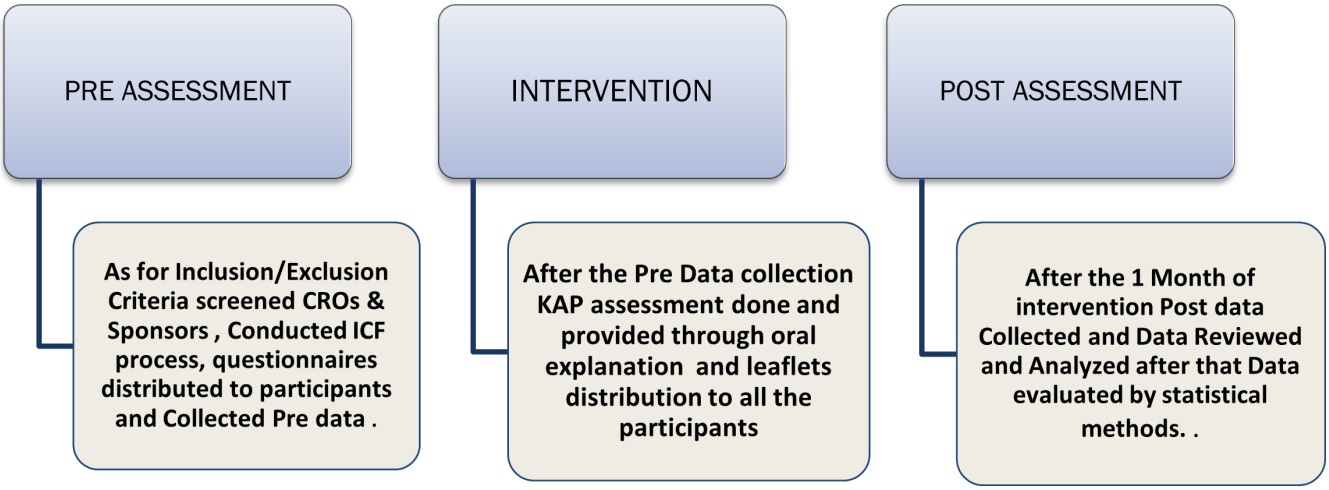

Figure 1: Study Procedure.

Table 1: Demographic profile of CRO and Sponsor representatives.

Demographic Data	Variables	N	%	Mean
Gender	Male	39	75	1.25
	Female	13	25	
Age	20-30	36	69.2	1.37
	31-40	13	25	
	41-50	3	5.8	
Role	CTA	8	15.4	3.92
	CRA	12	23.1	
	Senior CRA	16	30.8	
	QA Auditor/Manager	2	3.8	
	Project Manager	6	11.5	
	Data Analyst	2	3.8	
	Others	6	11.5	
Work Experience	1-05	43	82.7	1.25
	06-10	6	11.5	
	11-15	2	3.8	
	>16	1	1.9	
Educational Background	Medicine	3	5.8	2.37
	Pharma	38	73.1	
	Life Sciences/Allied Sciences	11	21.2	
Location of the company/State	KA	29	55.8	2.15
	MH	9	17.3	
	Gujarat	4	7.7	
	Andhra Pradesh	3	5.8	
	Telangana	2	3.8	
	Kerala	4	7.7	
	Tamil Nadu	1	1.9	
	Total	52	100	

(p<0.000). Awareness of potential misuse or misconduct in bio specimen research increased from 13.5% to 42.3% (p=0.007) and review of optional consent procedures showed a significant rise from 59.6% to 88.5% (p<0.001), while recognition of material transportation procedures' importance remained high without a significant change. The understanding that optional consent is mandatory in surplus bio specimen research remained consistent. Awareness of commercial uses of surplus bio specimen samples decreased significantly from 30.8% to 13.5% (p<0.002), while recognition of tissue commercialization as unethical increased from 69.2% to 92.3%. Regarding the process for disposing of excess biological specimens, preferences shifted toward the burning method. A significant association was found between the type of study conducted using samples for secondary research and genetic research, future research, or both (p=0.021). Most participants recognized the importance of sharing rare diseased data and uncurable data with other institutes and the main protocol allowing usage of samples only with clear optional research details and associated investigations remained consistent. Utilization of leftover bio specimens in clinical research for secondary/future research significantly increased from 15 to 44%. Overall, these findings highlight significant improvements in knowledge and perceptions of Pharmaceutical Sponsors regarding various aspects of bio specimen research. The comparisons of Pre and Post test values of knowledge are shown in Table 2.

Attitude Pre and Post analysis of Pharmaceutical Sponsors by using McNemar-Bowker Test

The comparison of pre- and post-attitude scores reveals shifts in viewpoints concerning various aspects of utilizing human bio specimens in research. For example, there is a significant increase in the proportion of respondents agreeing post-analysis compared to pre-analysis regarding the challenging nature of the consent process when using archived bio specimens for future research (from 26.9% to 57.7%, p<0.001). Similarly, there is a

Table 2: Shows the Pre and Post analysis knowledge of Pharmaceutical Sponsors using the McNemar-Bowker Test

Comparison of Pre and Post Knowledge Scores							
Test	**Pre n%**	**Post n%**	**Pre n%**	**Post n%**	**Pre n%**	**Post n%**	***p* Value**
Do you have knowledge about storing bio specimen samples for future research?	30(57.7)	43(82.7)	17(32.7)	5(9.6)	5(9.6)	4(7.7)	<0.003
Do you think Consent is mandatory for Secondary research purposes?	41(78.8)	47(90.4)	4(7.7)	1(1.9)	7(13.5)	4(7.7)	0.182
Is consent required for the utilization of surplus bio specimens in secondary or future research?	25(48.1)	46(88.5)	19(36.5)	4(7.7)	8(15.4)	2(3.8)	<0.000
Do you think human surplus bio specimens are useful for developing diagnostic and treatments for endemic diseases?	36(69.2)	49(94.2)	11(21.2)	3(5.8)	5(9.6)	0(0)	-
The clinical trial protocol outlines all necessary investigations of surplus bio specimens in secondary research.	16(30.8)	6(11.5)	31(59.6)	43(82.7)	5(9.6)	3(5.8)	0.29
Have you observed whether the patient's or Legally Authorized Representative's (LAR) prior consent was obtained before utilizing a surplus human bio specimen in research?	26(50)	48(92.3)	7(13.5)	3(5.8)	19(36.5)	1(1.9)	<0.000
Have you noticed any misuse or misconduct in human bio specimen research?	7(13.5)	22(42.3)	32(61.5)	26(50)	13(25)	4(7.7)	.007
Have you reviewed any optional consent procedures in bio specimen research?	31(59.6)	46(88.5)	7(13.5)	5(9.6)	14(26.9)	1(1.9)	<0.001
Do you consider Material Transportation procedures (MTA) essential in bio specimen research?	42(80.8)	50(96.2)	6(11.5)	2(3.8)	4(7.7)	0(0)	-
In surplus bio specimen research optional consent process is mandatory?	31(59.6)	46(88.5)	12(23.1)	6(11.5)	9(17.3)	0(0)	-
Have you noticed/heard of any commercial uses of surplus bio specimen samples in research?	16(30.8)	7(13.5)	30(57.7)	44(84.6)	6(11.5)	1(1.9)	<0.002

Comparison of Pre and Post Knowledge Scores									
Test	**Pre n%**		**Post n%**	**Pre n%**	**Post n%**	**Pre n%**	**Post n%**		***p* Value**
Do you know tissue commercialization is unethical in human surplus biospecimen research?	36(69.2)		48(92.3)	9(17.3)	4(7.7)	7(13.5)	0(0)		-
What do you do with Surplus bio specimens when conducting research as a researcher?	Discard		Store/Share for secondary research		Both A and B		Don't Know		-
	6(11.5)	2(3.8)	18(34.6)	4(7.7)	28(53.8)	44(84.6)	0(0)	2(3.8)	
What is the process for disposing of excess biological specimens in research?	Big hole method		Burning Method		Both A and B		Don't Know		-
	6 (11.5)	6 (11.5)	16 (30.8)	10 (19.2)	30 (57.7)	39 (75)	0(0)	0(0)	
What type of study is being done? If researchers use samples for secondary research.	Genetic Research		Future Research		Both A and B		Don't Know		.021
	7 (13.5)	4 (7.7)	9 (17.3)	9 (17.3)	9 (17.3)	9 (17.3)	9 (17.3)	9 (17.3)	
What kind of data/ samples are supposed to be shared with another institute in human Surplus bio specimen research?	Rare Diseased Data		Uncurable Data		Both A and B		Don't Know		-
	13 (25)	13 (25)	3 (5.8)	4 (7.7)	4 (7.7)	4 (7.7)	4 (7.7)	4 (7.7)	
In research collected Human bio specimen's samples can be used for future research.	The main protocol allows for the usage of samples only if optional research details and associated investigations are clearly mentioned.			It is necessary to obtain consent or a waiver from the institute for re-consent.			Don't know		-
	42(80.8)	49(94.2)		49(94.2)	2(3.8)		2(3.8)	1(1.9)	
What is the role of surplus human bio specimens in ongoing clinical research studies?	This is extremely beneficial for future research and has the potential to greatly enhance the quality of research outcomes.		Preserved tissues possess significance in the comparison of current and historical diseases.		All of the above		Don't know		-
	7 13.5	2 3.8	5 9.6	3 5.8	37 (71.2)	47 (90.4)	3(5.8)	0(0)	

Comparison of Pre and Post Knowledge Scores										
Test	**Pre n%**		**Post n%**	**Pre n%**	**Post n%**		**Pre n%**	**Post n%**		***p* Value**
What are the measures taken to avoid misuse of the specimen?	Subjected to rigorous oversight or close and careful observation to ensure compliance with established rules, regulations, or standards.		Embracing appropriate regulations and implementation.		All specimen lists are meticulously organized and regularly updated records or catalogs in research.		All of the above	Don't know		-
	14 (26.9)	0 (0)	7 (13.5)	0 (0)	5 (9.6)	0 (0)	26 (50)	52 (100)	0 0	0 0
How leftover bio specimens are utilized in clinical research?	For Secondary/ Future research		For Academic/ Teaching purposes		Preserving for further diagnostics		All Of the above	Don't know		-
	15 (28.8)	5 (9.6)	4 (7.7)	1 (1.9)	8 (15.4)	2 (3.8)	22 (42.3)	44 (84.6)	3 (5.8)	0 (0)

notable increase in agreement post-analysis concerning concerns about the difficulty arising from using human surplus bio specimens in research (from 55.8% to 65.4%, p=0.267). On the other hand, perceptions regarding the association of human bio specimen research with risks or harm for participants increased post-analysis (from 5.8% to 63.5%). The analysis also indicates shifts in opinions regarding the expectation of participants to receive their bio-sample results from research data, with a significant increase in agreement post-analysis (from 34.6% to 46.2%, p=0.004). Additionally, there is an increase in agreement regarding the belief that human bio specimen research is beneficial for society/the public (from 36.5% to 50.0%). However, opinions regarding whether the storage of data after patient treatment/ death is controversial or unethical remain relatively stable, albeit with a slight increase in agreement post-analysis (from 21.2% to 38.5%, p=0.059). In conclusion, these results suggest changing attitudes among pharmaceutical sponsors towards the ethical, practical and societal implications of utilizing human bio specimens in research settings. The comparisons of Pre and Post test values of Attitude are shown in Table 3.

Practice Pre and Post analysis of Pharmaceutical Sponsors by using McNemar-Bowker Test

The investigation used questionnaires to assess Pharmaceutical sponsors Pre and Post assessment. The McNemar-Bowker test was used to examine various aspects of surplus human bio specimens in research, including management, utilization and ethical considerations. It compares scores in various areas such as handling leftover tissue samples, research on bio specimens, compliance with regulations and measures for quality improvement. The percentage of sponsors who contacted central laboratory representatives for information on leftover tissue samples significantly increased from 50% before to 75% after (p=0.010). Meanwhile, the percentage of sponsors who discovered leftover tissue samples in central laboratories rose from 50% before to 73.1% after (p<0.003). The perception of satisfactory practices in human surplus bio specimen research improved from 36.5% before to 63.5% after (p<0.001). The recognition of misleading utilization of archived or preserved tissue samples notably increased from 51.9% before to 80.8% after (p<0.002). Awareness of challenges in protecting subjects' privacy decreased from 48.1% before to 7.7% after (p<0.000). The presence of specific guidelines for archival HSB specimens significantly rose from 28.8% before to 78.8% after (p<0.003). Recognition of stakeholders' misleading practices increased from 36.5% before to 65.4% after (p<0.005). The perception of adequate practices to address challenges during HSB research increased from 19.2% before to 82.7% after (p<0.000). The adoption of anti-commercialization practices and regulations increased from 61.5% before to 90.4% after (p<0.001). These findings provide valuable insights into the changes observed in pharmaceutical sponsors' practices and perceptions regarding bio specimen research, regulatory compliance and quality improvement measures before and after the intervention. The comparisons of Pre and Post test values of Practice are shown in Table 4.

Table 3: Shows the Pre and Post Attitudes of Pharmaceutical Sponsors using the McNemar-Bowker Test.

Comparison of Pre and Post Attitude Scores											
Test	**Pre (n %)**	**Post (n %)**	**Pre (n %)**	**Post (n %)**	**Pre (n %)**	**Post (n %)**	**Pre (n %)**	**Post (n %)**	**Pre (n %)**	**Post (n %)**	***p* Value**
Is the consent process challenging while using archived bio specimens for future research?	Strongly Agree		Agree		Neutral		Disagree		Strongly Disagree		
	14 (26.9)	30 (57.7)	2 (3.8)	11 (21.2)	10 (19.2)	1 (1.9)	8 (15.4)	5 (9.6)	18 (34.6)	5 (9.6)	<0.001
Does Using Human Surplus Bio specimen in a research or trial study lead to difficulty?	4 (7.7)	1 (1.9)	3 (5.8)	4 (7.7)	8 (15.4)	7 (13.5)	8 (15.4)	6 (11.5)	29 (55.8)	34 (65.4)	0.267
Human bio specimen research is associated with any risk/harm for participants.	0(0)	3(5.8)	0(0)	3 (5.8)	19 (36.5)	4 (7.7)	0 (0)	9 (17.3)	33 (63.5)	33 (63.5)	-
Do you think Researchers use human bio samples for secondary research/future research?	22 (42.3)	26 (50.0)	10 (19.2)	16 (30.8)	20 (38.5)	2 (3.8)	0 (0)	4 (7.7)	0 (0)	4 (7.7)	-
Misuse of HSB samples in research can affect research participation in future research	7 (13.5)	4 (7.7)	4 (7.7)	3 (5.8)	12 (23.1)	2 (3.8)	12 (23.1)	8 (15.4)	17 (32.7)	35 (67.3)	0.008
Do you think study participants will expect the bio-sample results from research data?	18 (34.6)	24 (46.2)	25 (48.1)	17 (32.7)	6 (11.5)	2 (3.8)	3 (5.8)	8 (15.4)	0 (0)	1 (1.9)	-
If they expect their own tissue sample results in research, will they get the results and benefits from the research?	5 (9.6)	18 (34.6)	18 (34.6)	19 (36.5)	14 (26.9)	2 (3.8)	6 (11.5)	7 (13.5)	9 (17.3)	6 (11.5)	0.004
Do you think human bio specimen research is beneficial for Society/the public?	19 (36.5)	26 (50.0)	29 (55.8)	16 (30.8)	4 (7.7)	3 (5.8)	0 (0)	5 (9.6)	0 (0)	2 (3.8)	
Do you think digital data storing of donor information is helpful for surplus bio specimen research?	8 (15.4)	21 (40.4)	17 (32.7)	11 (21.2)	11 (21.2)	2 (3.8)	10 (19.2)	13 (25.0)	6 (11.5)	5 (9.6)	0.01
Do you think, the storage of data after patient treatment/ Death is controversial or unethical?	4 (7.7)	5 (9.6)	4 (7.7)	3 (5.8)	11 (21.2)	3 (5.8)	22 (42.3)	21 (40.4)	11 (21.2)	20 (38.5)	0.059
In Human Research voluntary consent is mandatory, is it applicable to secondary research?	16 (30.8)	23 (44.2)	23 (44.2)	17 (32.7)	5 (9.6)	2 (3.8)	8 (15.4)	8 (15.4)	0 (0)	2 (3.8)	-

Comparison of Pre and Post Attitude Scores											
Test	**Pre (n %)**	**Post (n %)**	**Pre (n %)**	**Post (n %)**	**Pre (n %)**	**Post (n %)**	**Pre (n %)**	**Post (n %)**	**Pre (n %)**	**Post (n %)**	***p* Value**
In research, giving database access to outside researchers is practicable	1(1.9)	4 (7.7)	17 (32.7)	11 (21.2)	13 (25.0)	2 (3.8)	16 (30.8)	19 (36.5)	5 (9.6)	16 (30.8)	0.001
Do you think tissue donors are able to understand human surplus bio specimen research/ archiving of human tissue?	8 (15.4)	15 (28.8)	25 (48.1)	17 (32.7)	9 (17.3)	4 (7.7)	0 (0)	11 (21.2)	10 (19.2)	5 (9.6)	-
Abuse of human surplus bio specimen tissue affects the quality of research.	6 (11.5)	1 (1.9)	3 (5.8)	3 (5.8)	8 (15.4)	3 (5.8)	18 (34.6)	23 (44.2)	17 (32.7)	22 (42.3)	0.269
The study informed consent document includes any restrictions on the use of surplus bio specimens Eg: Tissue commercialization and misuse of a specimen.	1 (1.9)	0 (0)	2 (3.8)	6 (11.5)	8 (15.4)	2 (3.8)	15 (28.8)	17 (32.7)	26 (50.0)	27 (51.9)	-
IRB/IEC should provide special considerations in approving the submitted bio specimen collection tools and informed consent documents in research	29 (55.8)	30 (57.7)	20 (38.5)	17 (32.7)	3 (5.8)	2 (3.8)	0 (0)	3 (5.8)	0 (0)	0 (0)	-
Do you think is it necessary to record/maintain HSB samples associated data in a laboratory database in stored specimens?	26 (50.0)	25 (48.1)	12 (23.1)	17 (32.7)	4 (7.7)	4 (7.7)	8 (15.4)	3 (5.8)	2 (3.8)	3 (5.8)	0.103
Human tissue contains Genetic data so, is there are any chances of misusing human samples in research	14 (26.9)	14 (26.9)	24 (46.2)	22 (42.3)	2 (3.8)	1 (1.9)	10 (19.2)	11 (21.2)	2 (3.8)	4 (7.7)	0.517

DISCUSSION

In a country like India where people involving in advanced medical research have very less information about surplus bio specimen research, Regulatory agencies have a key role in educating them and minimize their misuses. For this, Pharmaceutical sponsors should be well knowledgeable regarding its utilization, handling and storage purposes in clinical research. Lack of knowledge can lead to misleading information while counseling and guiding sampling procedures during bio specimen research. In our study, we tried to assess and educate Pharmaceutical sponsors about Surplus bio specimen research and its challenges in clinical research. The results highlight shifts in Pharmaceutical Sponsors' knowledge, attitudes and practices in bio specimen research. There's increased awareness of sample storage and consent for secondary research, indicating better understanding of bio specimen management and ethics. However, understanding of investigations for surplus bio specimens in secondary research seems lacking, revealing potential regulatory knowledge gaps. Despite this, there's growing awareness of misuse risks and emphasis on ethics and compliance. Sponsors recognize the consent process challenges and prioritize ethical and safety considerations. They increasingly see societal benefits in human bio specimen research. Practices show better communication, handling and vigilance for ethics and compliance, enhancing quality improvement efforts.

A study in Amman, Jordan found that 98.0% of adult cancer patients were willing to donate their excess blood and tissue samples for research. The study also showed high willingness to donate blood for research (82.9%) and interest in receiving research results (84.9%). However, many patients were unaware of what happened to their samples, with only 23.4% having participated in medical research.[1] similarly our study focused

Table 4: Shows the Pre and Post analysis of Practices of Pharmaceutical Sponsors using the McNemar-Bowker Test.

Comparison of Pre and Post Practice Scores							
Test	**Pre n%**	**Post n%**	**Pre n%**	**Post n%**	**Pre n%**	**Post n%**	***p* Value**
Did you approach central laboratory representatives regarding leftover tissue sample information in research?	Yes		No		Don't Know		
	26 (50)	39 (75)	12 (23.1)	7 (13.5)	14 (26.9)	6 (11.5)	0.010
Are you find any leftover tissue samples remaining in the central laboratory representative's laboratory?	26 (50)	38 (73.1)	14 (26.9)	9 (17.3)	12 (23.1)	5 (9.6)	<0.003
As per your observation, is a satisfactory bio bank practiced in human surplus bio specimen research?	19 (36.5)	33 (63.5)	12 (23.1)	15 (28.8)	21 (40.4)	4 (7.7)	<0.001
Are there any Chances of misleading archived or preserved tissue sample utilization in research?	27 (51.9)	42 (80.8)	7 (13.5)	6 (11.5)	18 (34.6)	4 (7.7)	<0.002
As research stakeholders have you faced any difficulties / compromises in the practice of protecting the subject's privacy and; confidentiality?	7 (13.5)	4 (7.7)	25 (48.1)	43 (82.7)	20 (38.5)	5 (9.6)	<0.000
Do you practice any guidelines for using archived or retrieval HSBs samples?	37 (71.2)	41 (78.8)	8 (15.4)	6 (11.5)	7 (13.5)	5 (9.6)	0.079
Are there any specific and separate guidelines for the practice of archival Human Surplus Bio Specimens?	15 (28.8)	9 (17.3)	28 (53.8)	41 (78.8)	9 (17.3)	2 (3.8)	<0.003
Have you noticed/heard of any stakeholders misleading practice in maintaining and archiving surplus bio specimens in research?	19 (36.5)	34 (65.4)	17 (32.7)	12 (23.1)	16 (30.8)	6 (11.5)	<0.005

Comparison of Pre and Post Practice Scores							
Test	**Pre n%**	**Post n%**	**Pre n%**	**Post n%**	**Pre n%**	**Post n%**	***p* Value**
Are adequate practices for research stakeholders to overcome challenges during human surplus bio specimen research?	10 (19.2)	6 (11.5)	22 (42.3)	43 (82.7)	20 (38.5)	3 (5.8)	<0.000
Are you practicing anti-commercialization Practices and regulations in the laboratory?	32 (61.5)	47 (90.4)	8 (15.4)	3 (5.8)	12 (23.1)	2 (3.8)	<0.001
Are you suggesting the implementation of particular regulations for the collection, tracking, shipping and storage of biological samples?	38 (73.1)	49 (94.2)	5 (9.6)	2 (3.8)	9 (17.3)	1 (1.9)	<0.004
Do you think the practice of appropriate SOPs is there for the use of Human Surplus Bio specimen?	34 (65.4)	44 (84.6)	6 (11.5)	6 (11.5)	12 (23.1)	2 (3.8)	0.019
Do researchers or sponsors involved in human specimen studies utilize any electronic tracking systems for specimen research?	9 (17.3)	6 (11.5)	26 (50)	43 (82.7)	17 (32.7)	3 (5.8)	<0.000
Would you suggest implementing an electronic tracking system for human surplus bio specimen research?	42 (80.8)	45 (86.5)	6 (11.5)	5 (9.6)	4 (7.7)	2 (3.8)	0.423
Is it mandatory to practice material transport regulations/ MTA in bio specimen research?	33 (63.5)	48 (92.3)	3 (5.8)	2 (3.8)	16 (30.8)	2 (3.8)	<0.000
Do you employ a unique identification or numbering system to verify and manage surplus bio samples in clinical research?	29 (55.8)	50 (96.2)	9 (17.3)	1 (1.9)	14 (26.9)	1 (1.9)	<0.000

Comparison of Pre and Post Practice Scores																
Test	**Pre n%**		**Post n%**		**Pre n%**		**Post n%**		**Pre n%**		**Post n%**				***p* Value**	
Do you think Good Laboratory Practice and Good Clinical practices can improve the quality of bio specimen research?	34 (65.4)		46 (88.5)		7 (13.5)		4 (7.7)		11 (21.2)		2 (3.8)				0.013	
If you are practicing any guidelines for using archived or retrieval HSB samples, please mention the title of the guidelines.	ICMR Guidelines -2017		NABH-Laboratory Guidelines		Regulations of Bio banking Research		GLP-GCP Guidelines				All of the above				0.009	
	10 (19.2)	2 (3.8)	8 (15.4)	3 (5.8)	4 (7.7)	1 (1.9)	4 (7.7)	1 (1.9)			26(50)	45(86.5)				
If you are aware of leftover tissue remaining in the Research laboratory what is your action for that specific sample?	Suggesting to discard/ Requesting to return		Agreeing to secondary use/ Future use		All of the above				Don't know						<0.000	
	18 (34.6)	6 (11.5)	10 (19.2)	8 (15.4)	10(19.2)	37 (71.2)			14 (26.9)	1 (1.9)						
What kind of misleading practices have you heard/noticed Human Surplus Bio Specimens Research?	Misuses of HSB samples for personal gain		Commercialization of samples		Data manipulation and Misuses		Inadequate storage methods		All of the above						<0.002	
	12 (23.1)	3 (5.8)	7 (13.5)	4 (7.7)	6 (11.5)	1 (1.9)	6 (11.5)	1 (1.9)	21 (40.4)	43 (82.7)						

on pharmaceutical sponsors' knowledge and practices regarding Surplus bio-specimens pre and posts an intervention. Results showed improvements in understanding specimen storage, obtaining consent and recognizing specimen value. Sponsors also showed increased awareness of protocols and took measures to prevent unethical practices. Overall, the findings suggest a significant improvement in pharmaceutical sponsors' understanding and actions related to bio-specimen research after the intervention.

Warner TD *et al.*, conducted study on "Perspectives on Broad Consent for Research on Bio specimens: Insights from Donors at Four U.S. Medical Centers" revealed that the majority of donors felt adequately informed by consent forms regarding the future utilization of their bio specimens. While they generally endorsed the use of their specimens across diverse research domains, they expressed reservations regarding for-profit ventures and foreign research endeavors. Donors indicated a preference for expert committees to oversee research applications, displayed moderate interest in study outcomes and cited altruistic motives for their donations. Overall, donors endorsed the concept of broad consent for research endeavors similarly; participants in our study also affirmed their commitment to broad consent.[2] However, our respondents underscored the necessity of re-consent procedures, advocated for mandatory sharing of results and benefits with participants and stressed the importance of controlling biased utilization. Additionally, we recommend that all research protocols explicitly disclose the future or secondary use of samples.

Shenuka Singh *et al.*, conducted a study in South Africa to understand stakeholders' views on the ethical and legal dimensions of bio banking. They interviewed 25 participants including bio bankers, clinicians, researchers, postgraduates and ethics committee members. Their findings highlighted inconsistencies in consent models disconnect between researchers and donors, challenges in re-consenting minors, governance issues, sample/ data sharing challenges and inadequate benefit-sharing strategies. The study underscores the need for ongoing ethics education for stakeholders to improve their understanding of bio-banking ethics.[18] This finding is similar to the findings of our study where we compared knowledge, attitude and practices of the pharmaceutical sponsors' pre and post education with the study material and found that there is a significant improvement in the

KAP of pharmaceutical sponsors' in the post education category irrespective of their experience in the field.

Jeffrey peppercorn *et al*., Conducted study on attitudes of cancer clinical trial participants towards the use of their archived bio specimens for research beyond what was initially consented for. Conducted at the Massachusetts General Hospital Cancer Center, the survey revealed overwhelmingly positive attitudes towards biomedical research, with participants expressing willingness to donate tissue for broad purposes, alongside expectations of privacy protection for their health information. Despite scenarios where proposed research extended beyond the original consent scope, a majority of participants favored proceeding, emphasizing the importance of advancing science and trusting researchers. Notably, concerns over commercialization and non-welfare interests were acknowledged, suggesting a need for transparent governance and community involvement in bio bank decisions. The study underscores the necessity of respecting participant autonomy while navigating evolving scientific methodologies and ensuring informed consent aligns with contemporary research practices.[19] In this study, above study conducted a single-term survey, but in our research, we utilized both pre- and post-surveys with identical questionnaires. This finding aligns with our study's results, where we compared the knowledge, attitudes and practices of pharmaceutical sponsors pre- and post-educational intervention using the same study material. We observed a significant improvement in the KAP of pharmaceutical sponsors.

Rivera *et al*., conducted a study on bio specimen research, gathering 114 responses from experienced researchers. The study found diverse practices and perspectives on informed consent, IRB oversight, regulations and bio specimen sharing. Notably, researchers preferred a standardized consent form for future unspecified research. Concerns were raised about restrictive regulations and bureaucratic obstacles. Institutional practices and interpretations of regulations varied, despite IRBs allowing bio specimen sharing under specific conditions. The study emphasized the importance of efficient systems that protect donor rights and promote collaboration. It called for a balance between regulatory compliance and effective research practices, advocating for standardized approaches and increased education in bio specimen research ethics.[20] The above study focused and assessed investigator experiences, attitudes and practices on bio specimen research conducted a one-time survey, while our research involved both pre- and post-surveys using the questionnaires. Our results are consistent with this discovery, as we examined the knowledge, attitudes and practices of pharmaceutical sponsors pre- and post a method through educational intervention with the same study materials. We noted a notable enhancement in the KAP of pharmaceutical sponsors.

The current study findings indicate a positive shift towards ethical practices, regulatory adherence and quality control in bio specimen research by Pharmaceutical Sponsors, vital for maintaining integrity and ethical standards in biomedical research. Participants demonstrated comprehension of handling surplus bio specimens responsibly, emphasizing consent, ethical guidelines and the potential benefits for medical research. However, there's room for improvement in ensuring universal consent for secondary research and enhancing oversight to prevent misuse.

CONCLUSION

This study contributes to our understanding of how pharmaceutical sponsors view the use of surplus bio specimens in research. It emphasizes the need for standardized guidelines, informed consent and education to improve practices. This research sets the foundation for future initiatives addressing ethical concerns and promoting responsible utilization of surplus bio specimens in the pharmaceutical industry. The study identified a knowledge gap among sponsors, but there was improvement after the post-test. Education is recommended to enhance their understanding of sample management. Misuse and commercialization of samples require attention and clear guidelines should be established for managing unused samples and data. Efforts should focus on improving knowledge of researchers and sponsors regarding sample coding, data transmission and ethical considerations. Limited awareness of regulations and ethics in India should be addressed to ensure ethical practices and advance medical knowledge.

LIMITATIONS AND RECOMMENDATIONS

The study, despite offering valuable insights, has limitations such as a small sample size and a narrow geographic focus, potentially affecting the generalizability of findings. Furthermore, the study suggests the necessity for globally standardized ethical guidelines to address ethical concerns comprehensively.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

KAP: Knowledge, Attitude and practice, **HSBs:** Human Surplus Bio specimens, **PS:** Pharmaceutical sponsors, **ICMR:** Indian council of medical research, **IEC:** Institutional ethics Committee.

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